

AUG 16 2005

K051095

Optical Connection
Inc.

510(k) Summary

Submitter Information:

Optical Connection, Inc.
a subsidiary of St. Shine Optical Co., Ltd.
3315 Almaden Expressway, Suite 25
San Jose, CA 95118
Registration No. 3004182654

Contact Person: Garold L. Edwards, O.D., F.A.A.O.
Regulatory Consultant

Telephone: (408) 221- 3860
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Date Prepared: April 19, 2005

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens

Trade/Proprietary Names: 55 UV (methafilcon A) Soft
(Hydrophilic) Contact Lens for Daily Wear

55 UV Multifocal (methafilcon A) Soft (Hydrophilic)
Contact Lens for Daily Wear

55 UV Toric (methafilcon A) Soft (Hydrophilic)
Contact Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens

Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

The Saview 55 F (methafilcon A) Soft (Hydrophilic) Single Vision Contact Lens, the Saview 55 Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens and the Saview 55 Toric Contact Lens were selected as the predicate devices manufactured in the same facility, under the same quality system, using the same molding, tinting,

packaging and sterilization processes. The Frequency 55UV (methafilcon A) Soft (Hydrophilic) lenses manufactured by Aspect Vision Care Ltd. have been chosen as the predicate lens using the same UV absorbing monomer.

Description of Devices:

The 55 UV, 55 UV Multifocal, and the 55 UV Toric (methafilcon A) Soft (Hydrophilic) Daily Wear Contact Lenses are hemispherical flexible shells, which cover the cornea and a portion of the adjacent sclera. The 55 UV Contact Lens is available in a single vision lens design, the 55 UV Toric Contact Lens is available in a double slab-off back surface design and the 55 UV Multifocal Contact Lens is available in an aspheric lens design. The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). A UV absorbing compound, 2-[3-(2H-Benzotriazol-2-yl)-4-hydroxyphenyl] ethyl methacrylate, has been incorporated into the lens polymer. Lenses are tinted using the color additive Pigment Blue 15, ([Phthalocyaninato(2-)] copper).

Comparison to Predicate Device

| PARAMETER | 55 UV, 55 UV Multifocal, and 55 UV Toric Soft (hydrophilic) Contact Lenses for Daily Wear N/A | Saview 55 F and Saview Toric 55 (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear K020197/ K021295 | Saview 55 Multifocal (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear K030548 | Frequency 55 UV (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear K982997 |
|--|--|--|---|--|
| Submission number | N/A | K020197/ K021295 | K030548 | K982997 |
| Material | methafilcon A | methafilcon A | methafilcon A | methafilcon A |
| Material classification | Hydrophilic Lens Group 4 | Hydrophilic Lens Group 4 | Hydrophilic Lens Group 4 | Hydrophilic Lens Group 4 |
| Indication for use | myopia, hyperopia, presbyopia and astigmatism | myopia and hyperopia | myopia, hyperopia, and presbyopia | myopia, hyperopia and astigmatism |
| Water content | 55% | 55% | 55% | 55% |
| Visible light transmittance | 90.3% (93.3% @590 nm) | 97.6% | 97.6% | 93.6 % @590 nm |
| UV transmittance @280-315 nm: @316 – 380 nm: | 9.1% (2.435% 15.816%) | N/A | N/A | 5.0% (6.00% 4.09%) |
| Dk (35° C) | 18.9×10^{-11} | 19.5×10^{-11} | 19.5×10^{-11} | 14.0×10^{-11} |
| Powers | +4.00 D to -20.00 D; Continuous add power to +3.25 (55 UV Multifocal only); Cylinder powers -0.50 D to -2.50 D (55 Toric only) | +4.00D to -6.00 D (in 0.25 D steps) + 4.50D to +12.00D (in 0.50 D steps) 6.50D to - 20.00D (in 0.50D steps); Cylinder powers -0.50 D to -2.50 D (Saview Toric 55 only) | +12.00 to -20.00 D; Continuous add power to +3.25 | +12.00 to -20.00 D |
| Color | blue visibility, Pigment Blue #15 | blue visibility, Pigment Blue #15 | blue visibility, Pigment Blue #15 | aqua visibility, Reactive Blue #4 and Reactive Yellow #86 |
| Refractive Index | 1.410 | 1.3974 | 1.3974 | 1.4027 |
| Method of manufacture | Molded | Molded | Molded | Molded |

Indications for Use:

The **55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The **55 UV Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The **55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non- diseased eyes.

The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eye care practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the 55 UV, the 55 UV Multifocal, and the 55 UV Toric (methafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear, and to establish substantial equivalence to the predicate devices.

Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. The 55 UV lenses were extracted and evaluated for presence of residue. Results showed no evidence of unsafe amounts of residue in the extracts. Physicochemical testing of the 55 UV lenses demonstrated equivalency to the predicate devices.

Conclusion:

Information submitted in the 510(k) establishes that the 55 UV, the 55 UV Multifocal and the 55 UV Toric Contact Lenses (methafilcon A) have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Optical Connection, Inc.
A subsidiary of St. Shine Optical Co. Ltd.
c/o Garold L. Edwards, O.D., F.A.A.O.
Regulatory Consultant
2091 Upper Scenic Drive
Felton, CA 95018

Re: K051095

Trade/Device Name: 55 UV (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: July 22, 2005
Received: July 25, 2005

Dear Dr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, reading "David M. Whipple". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Optical Connection Inc

INDICATIONS STATEMENT

Device Names:

55 UV (methafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
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Prescription Use X OR Over-the-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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http://www.opticalconnection.com

(Division Sign-Off) Proud Member of the Shine Optical Group
Division of Ophthalmic Ear, Nose and Throat Devices Where You Don't Have to Settle for 20/20

510(k) Number K051095